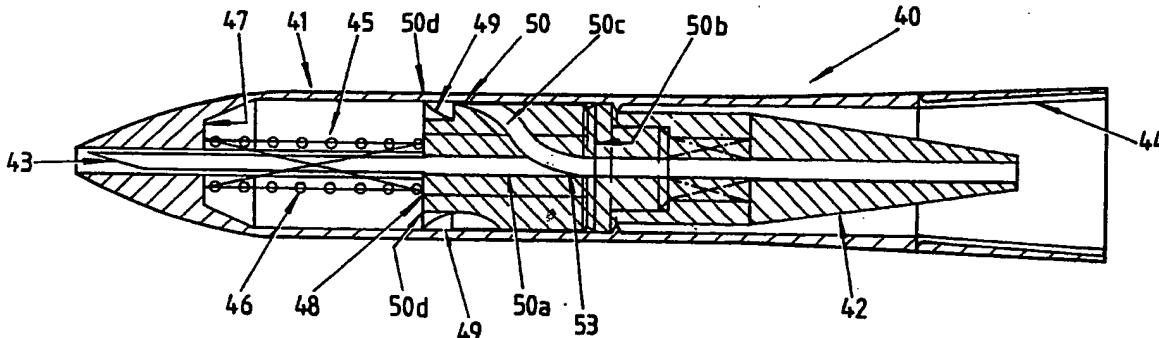




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 5/50, A61B 5/14, 10/00		A1	(11) International Publication Number: WO 91/11212 (43) International Publication Date: 8 August 1991 (08.08.91)
<p>(21) International Application Number: PCT/AU91/00035</p> <p>(22) International Filing Date: 1 February 1991 (01.02.91)</p> <p>(30) Priority data: PJ 8437 2 February 1990 (02.02.90) AU</p> <p>(71)(72) Applicants and Inventors: GILLILAND, Gerard, Philip [GB/AU]; 21 Lane Road, Ferntree Gully, VIC 3156 (AU). PARSONS, Joseph, Redvers, Buller [GB/AU]; 20 Moira Avenue, Ferntree Gully, VIC 3156 (AU).</p> <p>(74) Agent: WATERMARK; 1st Floor, The Atrium, 290 Burwood Road, Hawthorn, VIC 3122 (AU).</p>		<p>(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent), NO, PL, RO, SD, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US.</p> <p>Published <i>With international search report.</i></p>	
<p>(54) Title: A RETRACTABLE SHARP</p> 			
<p>(57) Abstract</p> <p>A non-reusable sharp device (40) is disclosed for injection or for taking body fluid or body tissue samples. The device comprises an inner body (42) having a sharp (43) attached thereto at one end and adapted at the other end (44) to be attached to a handle and an outer body (41) having bore therethrough adapted to receive the inner body (42) therein for slidable and rotational movement between the inner and outer body. The device may be operated from a first position in which the sharp is contained within the outer body via one or more second or intermediate positions, in at least one of which intermediate position the sharp is exposed for use to a third position in which the sharp is contained and locked within the outer body. The device may be automatically retractile. The device includes cooperating groove (50) and projections (49) to control the operation of the device.</p>			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	US	United States of America
DK	Denmark				

A RETRACTABLE SHARP

The present invention relates to a non-reusable sharp, needle or sampling device and relates particularly but not exclusively to an automatically retractile non-reusable hypodermic needle for introduction of fluids to 5 or sampling of fluids from a human or other animal body.

The device may also find application in providing a non-reusable knife, scalpel or other body sampling cutting blade implement (i.e. a sharp) in which the blade or sharp is in an unexposed configuration as received, is able to be 10 operated to expose the sharp for use and may subsequently be operated to lock the sharp within the body of the device to prevent accidental injury and to prevent reuse of the device. The form of the invention described in detail 15 relates to a needle device however the needle of the device could equally well be replaced by a sharp for obtaining other body samples.

The risks of infection from reuse of needles and 20 syringes and from accidental needle stick injuries are well known and many attempts have been made in recent times to overcome these problems. Numerous patents are directed to attempting to overcome the problems of needle stick injury from and multiple use of syringes and needles.

Representative examples of such patents are US patents 25 4813940 (Parry), 4846809 (Sims), 4872552 (Unger), 4887998 (Martin), 4897083 (Martell) and 4906236 (Alberts).

Of particular relevance to the problem of needle stick injuries and prevention of reuse of syringes is US 30 patent 4813940 (AU patent application 81406/87) ("Parry") which is directed to needles and needle and syringe combinations which attempt to overcome the disadvantages of the prior art. Parry discloses in one embodiment a retractable needle device in which the needle is biassed by spring means towards an extended position in which the needle, which may be mounted on a slidable inner boss 35 portion, is enclosed within a protective outer sleeve portion. The needle is exposed by exerting pressure against the spring bias means in order that injections may be given

- 2 -

5 or blood samples taken. There is no disclosure of means to enable the device to be retained (temporarily) in the exposed or contracted configuration without the device being manually held in that configuration against the spring bias means by the operation of the device.

10 It is an object of the present invention to provide a retractable non-reusable needle device which overcomes or alleviates at least some if not all of the disadvantages of the devices of the prior art.

15 The present invention therefore provides a non-reusable sharp device for taking body tissue samples which comprises an inner body having a sharp attached thereto at one end and adapted at the other end to be attached to a handle and an outer body having a bore therethrough adapted to receive the inner body therein for slidable and rotational movement between the inner and outer body said device being operable from a first position in which the sharp is contained within the outer body via one or more second or intermediate positions, in at least one of 20 which intermediate position the sharp is exposed for use to a third position in which the sharp is contained and locked within the outer body.

25 The present invention also provides a non-reusable needle device for injection or for withdrawal of body fluid samples adapted to be connected to a syringe or to body fluid collection device which comprises at least two body sections forming an inner body having a needle attached thereto and an outer body slidably and rotatably mounted about the inner body said device being operable from a first 30 position in which the needle is retracted and contained within the outer body, via a second position in which the needle extends beyond the outer body and is releasably engaged in an in use configuration to a third position in which the needle is locked in a retracted configuration 35 within the outer body.

- 3 -

The present invention further provides a non-reusable needle device for injection or for withdrawal of body fluid samples which comprises an inner body having a needle attached thereto at one end and adapted at the other 5 end to be attached to injector or body sampling means and an outer body having a bore therethrough adapted to receive the inner body therein for slidable and rotational movement between the inner and outer body said device being operable from a first position in which the needle is contained 10 within the outer body via one or more second or intermediate positions at which at least one of which positions the needle is exposed for use to a third position in which the needle is contained and locked within the outer body.

Preferably the device includes bias means to bias 15 the device towards the first and/or third positions. Preferably the bias means comprises a spring disposed within the outer body. Preferably the inner body is disposed substantially within an axially disposed bore in the outer body. Preferably movement of the device from the first to 20 the third position is controlled by groove means formed in one of said body sections and groove follower means formed on the other of said body sections. Preferably the groove means is of varying depth along its length and includes step means to restrict relative movement between the groove follower and the groove means to one direction and at least 25 one step means.

Preferably the step means locks the device in said third position such that the device cannot be operated to expose the needle.

30 Preferably the groove additionally includes one or more projections to restrain the device against force of the bias means in any one of a plurality of positions intermediate said first and third positions. Preferably the configuration of the grooves and the positions of the steps 35 and beads causes the device to automatically retract to the locked position when the device is removed from the syringe

- 4 -

or other attachment. Preferably follower means is biassed towards the groove means.

Referring to Figs. 1 and 2 there is shown a non-reusable needle device 10 comprising a generally cylindrical outer body 11 and a generally cylindrical inner body 12. The outer body 11 has an axially disposed bore 13 adapted to slidably accommodate inner body 12 therein. Inner body 12 includes an axially disposed bore 14 therethrough to permit fluid communication between needle 15 fixed to the forward end 16 thereof and connection means 17 at rearward end 18 adapted to be connected to e.g. a syringe or body fluid collection device (not shown).

Outer body 11 includes towards the forward end 19 an annular flange 20 within the bore 13 and longitudinal groove 21 formed within the walls of the bore 13. The outer body includes at its rearward end 22 a further inwardly directed annular flange 23.

Inner body 12 includes at end 16 a forwardly projecting boss 24 with a flange 25 disposed rearwardly thereof. Disposed rearwardly of the flange 25 on inner body 12 is a pair of diametrically opposed groove followers 26 comprising projections 27 and resilient connectors 28. The rear end of the groove followers 26 includes step 29. Flange 25 is dimensioned to readily slide within the bore 13 of diameter "d" in the outer body 11.

Disposed within outer body 11 about needle 15 and boss 24 is a spring 30 which extends between annular flange 20 on the outer body and flange 25 on the inner body to bias the needle in a retracted configuration as shown in Fig. 2 such that needle 15 is entirely within outer body 11. Step 29 on groove follower 26 abuts flange 23 on the outer body 11 to restrain the inner body 12 within the outer body 11. The inner body and outer body are dimensioned such that the inner body snap fits through the annular flange 23 on assembly of the parts.

Fig. 1a is a cross-sectional view and Fig. 1b a plan view of the groove 21 along its length from B to B'.

- 5 -

Referring to Fig. 3 in conjunction with Figs. 1a and 1b the operation of the non-reusable needle device 10 will be described in more detail. Fig. 3a shows the needle device in cross-section in a retracted position ready for use, Fig. 3b shows the needle device in cross-section in an exposed configuration ready for use, Fig. 3c shows the needle device in cross-section in an intermediate configuration prior to retraction following use and Fig. 3d shows the needle device in cross-section in the fully retracted and locked configuration. In Fig. 3 the plane of the cross-sectional view of the inner body portion is constant whilst the plane of cross-section of the outer body in Figs. 3a and 3b is at right angles to the plane of cross-section of the outer body in Figs. 3c and 3d. That is to say in Fig. 3 the inner body does not rotate about its axis whilst the outer body as shown in Figs. 3c and 3d is rotated about its axis by 90° with respect to the outer body as shown in Figs. 3a and 3b.

In Fig. 3a the inner body 12 is biased by spring 30 so that the needle 15 is fully retracted within outer body 11 with step 29 on groove followers 26 abutting against flange 23 on outer body 11 due to the bias of spring 30. The projections 27 of followers 26 are biased outwardly due to the resilience of connectors 28 within longitudinal groove portion 21a. As the needle device is fitted to e.g. a syringe (not shown) the device moves from the configuration of Fig. 3a to that of Fig. 3b. Projections 27 are depressed inwardly as they move along inclined ramp 31 of groove portion 21b from level (i) to level (ii) until the projections 27 pass over step 32 and into groove portion 21c at level (i). Abutment of projections 27 against step 32 prevents return of the device to the configuration of Fig. 3a and holds the needle 15 exposed for use. Once the needle has been used the outer body is rotated 90° with respect to the inner body to the configuration as shown in Fig. 3c. Projections 27 pass along circumferential groove 21c at

- 6 -

level (i) and then along longitudinal groove portion 21d due to bias of the spring 30. The projections 27 are depressed inwardly as they move along inclined ramp 33 of groove portion 21d from level (i) to level (ii) until the
5 projections pass over step 34 to level (i) to lock the needle device in the retracted configuration as shown in Fig. 3d by means of abutment of projections 27 in groove portion 21e behind step 34 and with step 29 on groove follower 26 restrained also within groove portion 21e by
10 outer body flange 23.

Referring to Fig. 4 there is shown an alternative construction of non-reusable needle device 40 including outer body 41 having inner body 42 slidably mounted therein. Inner body 42 has affixed thereto needle 43 such that there
15 is fluid communication between needle 43 and syringe attachment means 44. Inner body 42 is slidably mounted within bore 45 of outer body 41. Spring 46 disposed between inner end face 47 of the bore 45 of the outer body and forward end 48 of the inner body 42.

20 Outer body has resiliently mounted within bore 45 a groove follower 49 adapted to fit within and follow groove 50 in the inner body 42 as will be described later. Inner body 42 is designed to snap fit within bore 45 of outer body 41 and be held in the retracted configuration with needle
25 43 entirely within outer body 41 by bias of spring 46 retaining rearward face 51 of inner body 42 abutting against stop 52 in the form of a circumferential bead on the outer body 41 within the bore 45. As the needle device is drawn on to a syringe (not shown), inner body 42 is caused to move
30 forward relative to outer body 41 and against the bias of spring 46. Follower 49 moves along grooved portion 50a and is restrained in groove portion 50b by way of a circular twisting motion of the inner body 42 with respect to outer body 41. The device is thus fixed in a configuration ready
35 for use with the needle 43 fully extended. In the Fig. the

- 7 -

device is shown in the final retracted and locked position and includes two sets of grooves 50 and followers 49.

As the needle device is removed from the syringe, the bias of spring 46 causes the follower to return 5 automatically back along groove portion 50b until step 53 is reached which diverts the follower 49 along groove portion 50c where a further groove step 50d restrains the device in the retracted configuration as shown such that the needle 43 cannot be re-extended and reused.

10 In the configuration of Fig. 4 it will be seen that the needle device of the invention is moved from the retracted to the exposed configuration as the device is attached to a syringe (not shown) by pressure of the end of the syringe against the tapered (right hand) end of the 15 inner body 42. Detachment of the needle device from the syringe permits the device to return to the retracted configuration with the needle locked within the outer body by means of cooperation between the groove follower 49 and groove 50.

20 Referring to Fig. 5 there is shown a further variant of needle device similar to that as described in Fig. 4. Fig. 5a is a plan view of the groove 63. The device 60 includes outer body 61 and inner body 62 slidably mounted therein as previously described in relation to Fig.

25 4. The inner body 62 includes a "Z plan" groove 63 disposed therein. The inner body as before has needle 65 attached thereto. Spring 64 is also provided to bias the device towards the retracted configuration wherein the needle 65 is contained and restrained wholly within the outer body 61.

30 Follower 66 resiliently mounted as before on the inside of the wall of outer body 61 follows groove 63 as previously. The device is initially supplied with the follower at groove portion 63a with the needle fully retracted within the outer body 61 as shown. Placement of the needle device on, for

35 example a syringe (not shown) causes outer body 61 to slide over inner body 62 guided by passage of follower 66 within

- 8 -

groove 63 from groove portion 63a to groove portion 63b. A slight twist of the outer body 61 with respect to inner body 62 causes the follower to rest in groove portion 63c. The follower is releasably retained in groove portion 63c by 5 means of bead 67 over which follower 66 snap fits. In this configuration the needle 65 is fully extended ready for use and held in position due to the constraint of the follower 66 in groove portion 63c with the assistance of bead 67. Once the needle has been used the device is rotated as 10 explained above to release follower 66 over bead 67 and the device operated so that follower 66 returns along groove 63b to 63a whereby the needle 63 is again withdrawn to within outer body 61. The inner body 62 is then rotated with respect to the outer body 61 so that the follower 66 passes 15 over bead 68 and is forced by the resilient means into groove portion 63d which projects deeper or further into the inner body 62 than the remaining portions of groove 63. The used needle device 60 is thus locked in a retracted configuration with the needle 65 completely contained within 20 the outer body 61 by cooperation between groove 63 and follower 66.

In the devices of Figs. 1 to 3 and 5 as distinct from the device of Fig. 4 the attachment of the needle device to the syringe (or other device) does not necessarily 25 cause the needle device to be moved from the first retracted configuration to the second "in use" configuration depending on whether or not the device is held by the inner or outer body portions. Separate manipulation of the needle device is required after the needle device is attached to the 30 required syringe or other sampling device depending on whether injection or body fluid sampling is to be conducted. It will be seen that by holding the device by the inner body portion the device may be attached to a syringe without the risk of the needle being exposed or contaminated.

- 9 -

The device of Figs. 1 to 5 may additionally contain bead means or other projections within the groove to hold the device in any one of a plurality of positions between the initial retracted configuration and the final locked 5 retracted configuration.

It will be seen that with appropriate positioning of these grooves and beads it is possible to construct a device which automatically returns to the locked retracted configuration when the device is removed from the syringe or 10 other attachment.

The device may be constructed of any suitable materials. For example the needle and spring may be of suitable stainless steel. The inner and outer body means may be of any suitable synthetic plastics material able to 15 be sterilized in the usual manner.

20

25

30

35

- 10 -

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A non-reusable needle device for injection or for withdrawal of body fluid samples adapted to be connected to a syringe or to a body fluid collection device which comprises at least two body sections forming an inner body having a needle attached thereto and an outer body slidably and rotatably mounted about the inner body said device being operable from a first position in which the needle is retracted and contained within the outer body, via a second position in which the needle extends beyond the outer body and is releasably engaged in an in use configuration to a third position in which the needle is locked in a retracted configuration within the outer body.
2. A device as claimed in claim 1 which includes bias means to bias the device towards the first and/or third positions.
3. A device as claimed in claim 1 or 2 in which the bias means comprises a spring disposed within the outer body.
4. A device as claimed in claim 1, 2 or 3 in which the inner body is disposed substantially within an axially disposed bore in the outer body.
5. A device as claimed in claim 1, 2, 3 or 4 in which movement of the device from the first to the third position is controlled by groove means formed in one of said body sections and groove follower means formed on the other of said body sections.
6. A device as claimed in any one of claims 1 to 5 in which said groove means is of varying depth along its length and includes step means to restrict relative movement

- 11 -

between the groove follower and the groove means to one direction.

7. A device as claimed in claim 6 in which there is at least one step means.

8. A device as claimed in claim 6 or 7 in which said step means locks the device in said third position such that the device cannot be operated to expose the needle.

9. A device as claimed in 6, 7 or 8 in which the groove additionally includes one or more projections to restrain the device against force of the bias means in any one of a plurality of positions intermediate said first and third positions.

10. A device as claimed in any one of claims 5 to 8 in which the follower means is biassed towards the groove means.

11. A non-reusable needle device for injection or for withdrawal of body fluid samples which comprises an inner body having a needle attached thereto at one end and adapted at the other end to be attached to injector or body sampling means and an outer body having a bore therethrough adapted to receive the inner body therein for slidable and rotational movement between the inner and outer body said device being operable from a first position in which the needle is contained within the outer body via one or more second or intermediate positions at which at least one of which positions the needle is exposed for use to a third position in which the needle is contained and locked within the outer body.

12. A device as claimed in claim 11 which includes bias means to bias the device towards the first and/or third positions.

- 12 -

13. A device as claimed in claim 11 or 12 in which the bias means comprises a spring disposed within the outer body.

14. A device as claimed in claim 11, 12 or 13 in which the inner body is disposed substantially within an axially disposed bore in the outer body.

15. A device as claimed in claim 11, 12, 13 or 14 in which movement of the device from the first to the third position is controlled by groove means formed in one of said body sections and groove follower means formed on the other of said body sections.

16. A device as claimed in any one of claims 11 to 15 in which said groove means is of varying depth along its length and includes step means to restrict relative movement between the groove follower and the groove means to one direction.

17. A device as claimed in claim 16 in which there is at least one step means.

18. A device as claimed in claim 16 or 17 in which said step means locks the device in said third position such that the device cannot be operated to expose the needle.

19. A device as claimed in claim 16, 17 or 18 in which the groove additionally includes one or more projections to restrain the device against force of the bias means in any one of a plurality of positions intermediate said first and third positions.

20. A device as claimed in any one of claims 15 to 18 in which the follower means is biased towards the groove means.

- 13 -

21. A non-reusable sharp device for taking body tissue samples which comprises an inner body having a sharp attached thereto at one end and adapted at the other end to be attached to a handle and an outer body having a bore therethrough adapted to receive the inner body therein for slidable and rotational movement between the inner and outer body said device being operable from a first position in which the sharp is contained within the outer body via one or more second or intermediate positions, in at least one of which intermediate position the sharp is exposed for use to a third position in which the sharp is contained and locked within the outer body.

22. A device as claimed in claim 21 which includes bias means to bias the device towards the first and/or third positions.

23. A device as claimed in claim 21 or 22 in which the bias means comprises a spring disposed within the outer body.

24. A device as claimed in claim 21, 22 or 23 in which the inner body is disposed substantially within an axially disposed bore in the outer body.

25. A device as claimed in claim 21, 22, 23 or 24 in which movement of the device from the first to the third position is controlled by groove means formed in one of said body sections and groove follower means formed on the other of said body sections.

26. A device as claimed in any one of claims 21 to 25 in which said groove means is of varying depth along its length and includes step means to restrict relative movement between the groove follower and the groove means to one direction.

- 14 -

27. A device as claimed in claim 26 in which there is at least one step means.
28. A device as claimed in claim 26 or 27 in which said step means locks the device in said third position such that the device cannot be operated to expose the needle.
29. A device as claimed in 26, 27 or 28 in which the groove additionally includes one or more projections to restrain the device against force of the bias means in any one of a plurality of positions intermediate said first and third positions.
30. A device as claimed in any one of claims 25 to 28 in which the follower means is biased towards the groove means.

1/6

Fig 1.

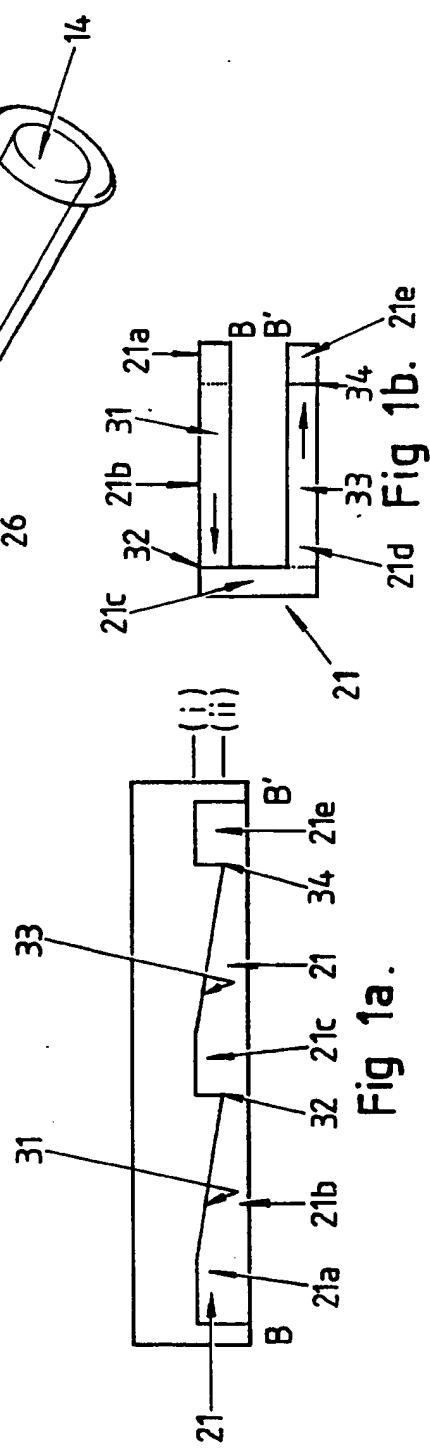
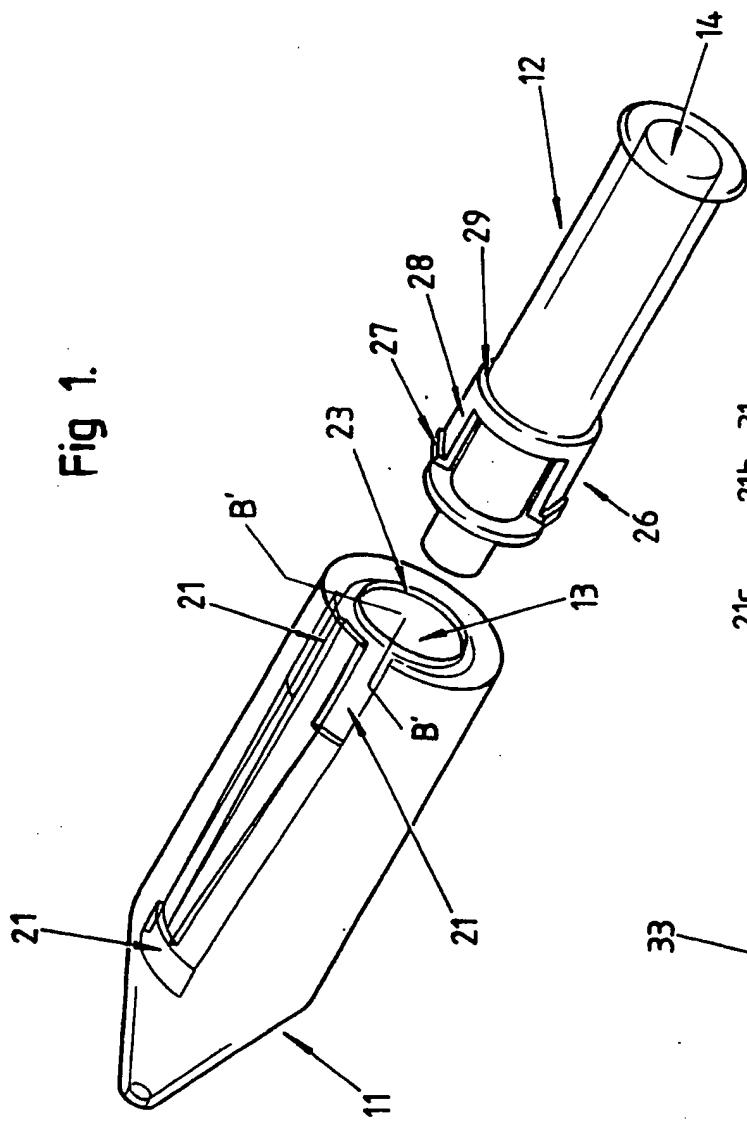


Fig 1a.

2/6

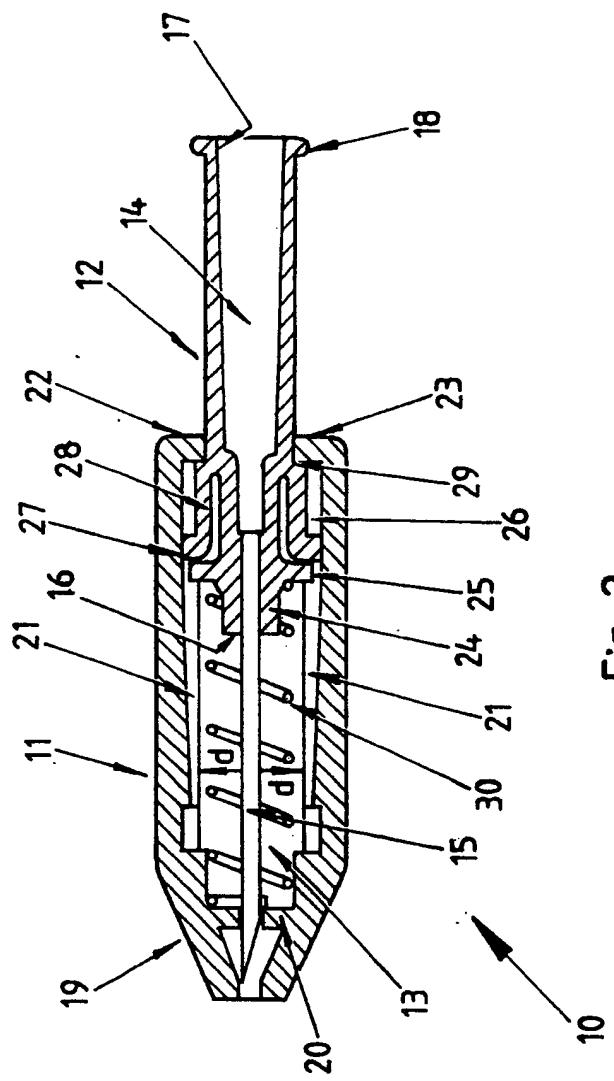


Fig 2.

3/6

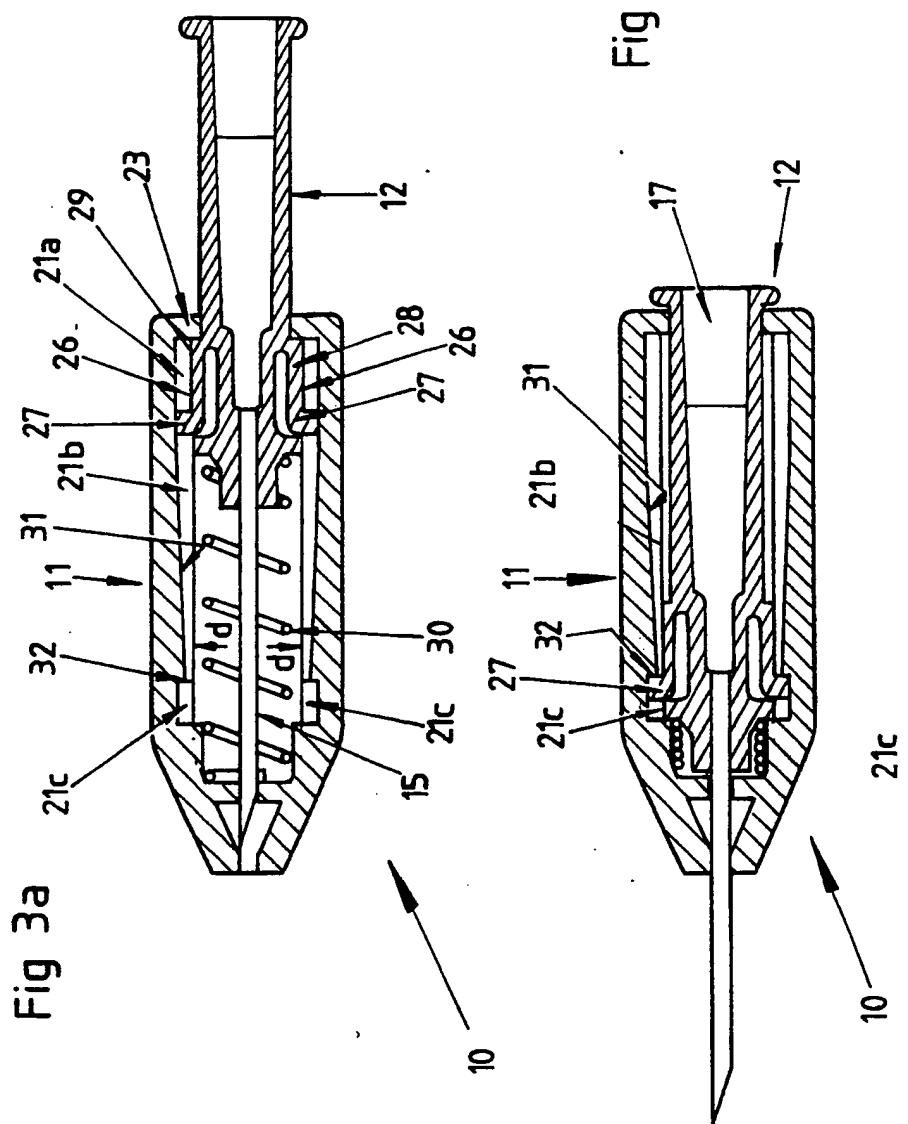


Fig. 3c.

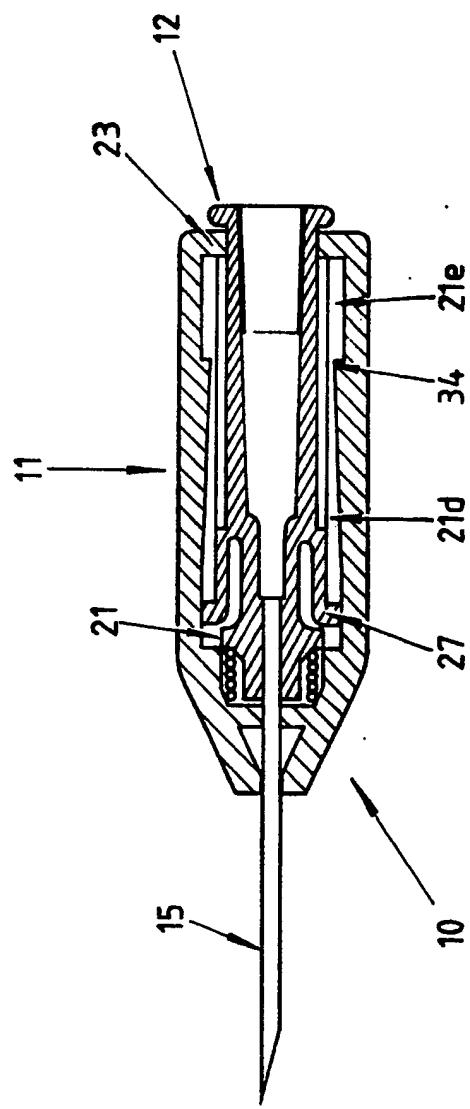
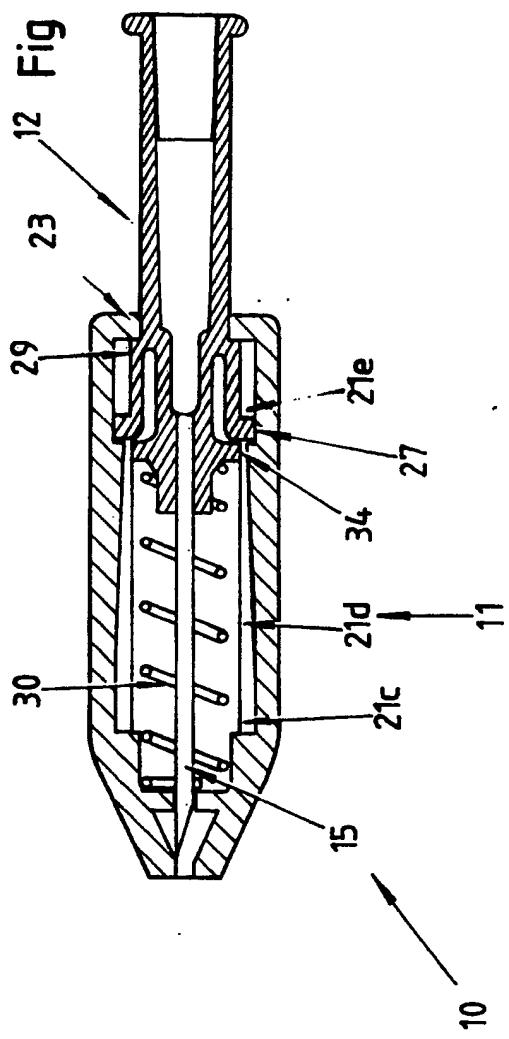
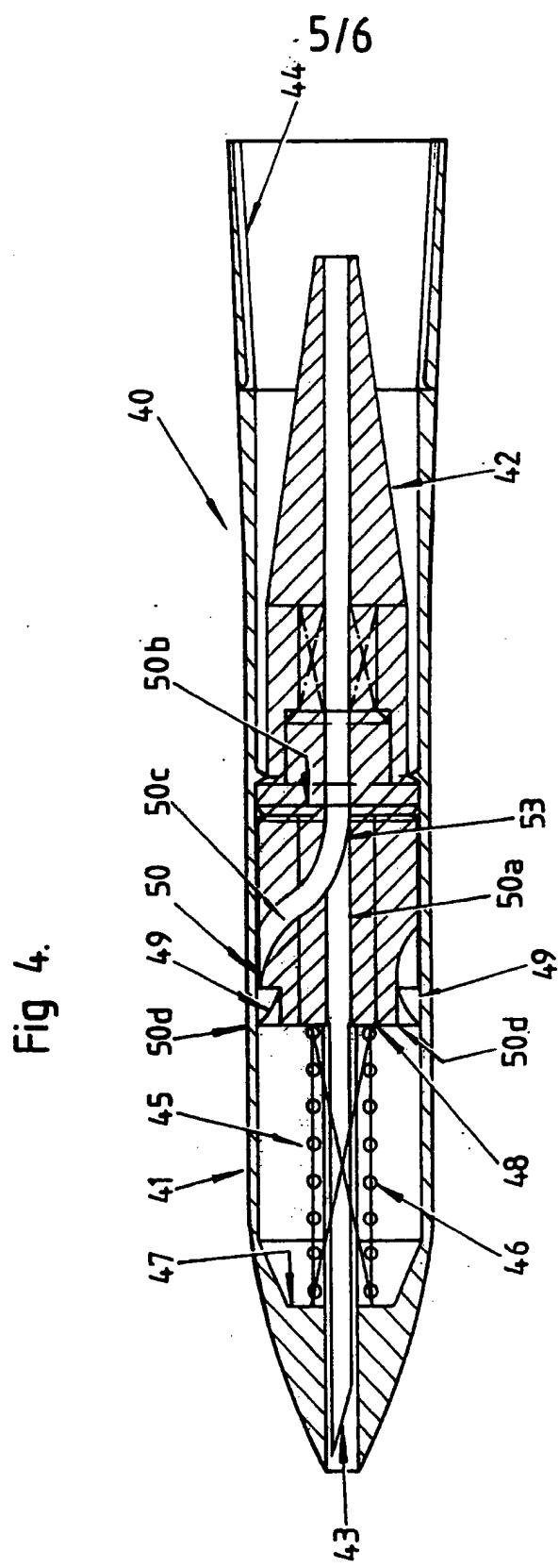


Fig. 3d. 4/6





6/6

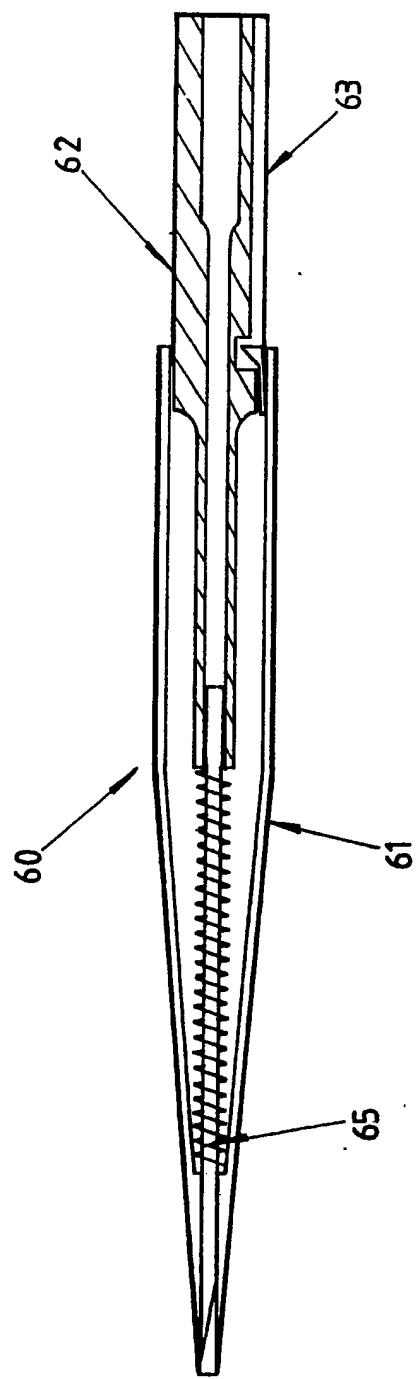
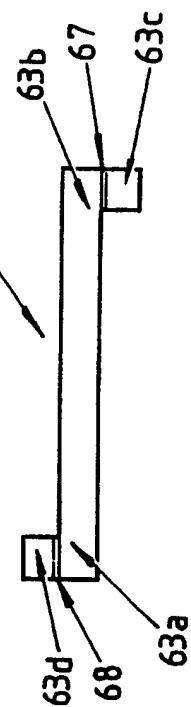


Fig. 5.

Fig 5a.



INTERNATIONAL SEARCH REPORT

International Application No. PCT/AU 91/00035

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 6

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl. ⁵ A61M 5/50 A61B 5/14, 10/00

II. FIELDS SEARCHED

Minimum Documentation Searched 7

Classification System	Classification Symbols
IPC	A61M 5/32, 5/50 A61B 5/14, 10/00

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched 8

AU: IPC as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT 9

Category*	Citation of Document, ¹¹ with indication ₁₂ where appropriate, of the relevant passages	Relevant to Claim No 13
X	AU,A, 60696/86 (DOMEROWSKI) 9 August 1985 (09.08.85). See pages 8-10	(1-5, 11-15)
X	US,A, 4801295 (SPENCER) 31 January 1989 (31.01.89). See abstract, columns 1 and 2 and figures 7-10	(1, 4-8, 11, 14-18)
X	US,A, 4702738 (SPENCER) 27 October 1987 (27.10.87)	(1, 4-8, 11, 14-18)
Y	See abstract and columns 1 and 2	(6, 7, 8)
P,X	US,A, 4908023 (YUEN) 13 March 1990 (13.03.90)	(1, 4, 11)
P,Y	See abstract and column 2	(6, 7, 8)
P,X	US,A, 4923446 (PAGE et al) 8 May 1990 (08.05.90)	(1, 4-5, 11, 14-15)
P,Y	See column 2 and figures 1-4B	(6-8, 16-18)
P,X	US,A, 4911693 (PARIS) 27 March 1990 (27.03.90)	(1-5, 11-15)
P,Y	See columns 1 and 2 and figures 2-4	(6-9, 16-19)
P,Y	US,A, 4915702 (HABER) 10 April 1990 (10.04.90). See column 1, lines 50-64; column 2, lines 31-46; and figures 10-13	(1, 4-8, 11, 15-18)

* Special categories of cited documents: 10	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	
"E" earlier document but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search 11 April 1991 (11.04.91)	Date of Mailing of this International Search Report 22 April 1991
International Searching Authority Australian Patent Office	Signature of Authorized Officer A HENDRICKSON 

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category*	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
P,Y	US,A, 4900311 (STERN et al) 13 February 1990 (13.02.90). See column 2, Lines 53-58 and figures 5-7	(1-9, 11-18)
Y	US,A, 4790827 (HABER et al) 13 December 1988 (13.12.88). See column 1, Lines 50-64; column 2, Lines 31-46; and figures 10-13	(1, 4-8, 11, 15-18)
Y	US,A, 4666435 (BRAGINETZ) 19 May 1987 (19.05.87). See column 6 and figure 6	(1, 4-8, 11, 14-18)
Y	US,A, 4752290 (SCHRAMM) 21 June 1988 (21.06.88). See column 2 and figures 1-3	(1, 4, 11)
Y	EP,A, 0350186 (SHERWOOD MEDICAL COMPANY) 10 January 1990 (10.01.90). See column 2, Lines 40-54; column 4, Lines 44-56; and column 14, Lines 13-32	(1, 4-8, 11, 14-18)
P,Y	WO,A, 90/07349 (VADHER) 12 July 1990 (12.07.90). See pages 8-10	(1-5, 11-15)
P,Y	AU,A, 33809/89 (MCNAUGHTON) 1 November 1990 (01.11.90). See pages 3, 6 and figure 2	(1, 4-8, 11, 14-18)
A	US,A, 4735202 (WILLIAMS) 5 April 1988 (05.04.88). See figures 1-3	21-30
A	US,A, 4735203 (RYDER et al) 5 April 1988 (05.04.88). See column 2, Lines 15-36; column 4, Lines 23-46; column 6, Lines 32-58 and figures 2-5 and 11	21-30

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. [] OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE 1

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [] Claim numbers ..., because they relate to subject matter not required to be searched by this Authority, namely:

2. [] Claim numbers ..., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [] Claim numbers ..., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4 (a):

VI. [] OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING 2

This International Searching Authority found multiple inventions in this international application as follows:

1. [] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. [] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. [] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. [] As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- [] The additional search fees were accompanied by applicant's protest.
- [] No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 91/00035

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Members			
AU	60696/86	EP	212906	JP	62038140
US	4653513				
AU	33809/89				
US	4702738	CA	1268679	EP	250104
US	4801295				
US	4908023				
US	4923446	US	4943282		
US	4911693				
US	4915702	BR	8802014	DK	2269/88
		JP	63317160	NZ	224372
		ZA	8802903	US	4790827
US	288879				
US	4758231				
US	4892523				
US	4900311	AU	47489/90	DK	1875/90
		NO	903450	WO	9006142
US	397845				
US	4801295	CA	1268679	EP	250104
US	4702738				
US	4790827	BR	8802014	DK	2269/88
		JP	63317160	NZ	224372
		ZA	8802903	US	4892523
US	288879				
US	4758231				
US	4915702				
US	4666435				
US	4752290	US	4826491		

END OF ANNEX/CONTINUED

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 91/00035 (CONTINUED)

Patent Document Cited in Search Report		Patent Family Members		
EP	350186	AU 37065/89	DK	3154/89
WO	9007349	AU 48205/90	US	4988339
US	4735202			
US	4735203	EP 274869		

END OF ANNEX

This Page Blank (uspto)